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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,697	09/15/2003	William J. Boyle	ACS 65470 (2309D)	9777

24201 7590 12/01/2006

FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER	
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ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 12/01/2006

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/662,697
Filing Date: September 15, 2003
Appellant(s): BOYLE ET AL.

Thomas Majcher
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/17/06 appealing from the Office action mailed 6/15/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,171,327	Daniel et al.	1-2001
5,201,757	Heyn et al.	4-1993

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-40,42-50, and 52-74 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,171,327 to Daniel et al.

Daniel illustrates a catheter system in Figures 20 and 21 that is designed for recovery of an embolic filter (21) that is disposed on a guide wire (26). The retrieval device includes an inner catheter (172 in Figure 20) that extends distally beyond a recovery sheath (151). The recovery sheath (151) tracks over the distal portion of the inner catheter to retrieve the filter (21). Figure 19 illustrates this function with a different embodiment of the device, but the embodiment in Figure 20 also performs this function. Daniel explains that the distal portion of the inner catheter (172) is made of flexible material (column 8, lines 61-67). As evidenced by the fact that the recovery sheath (151) is capable of deforming the distal end (180,280) of the inner catheter when pushed distally to retrieve the filter, the distal portion of the inner catheter is more flexible than the recovery sheath (151). Each catheter has a control

handle attached to its proximal end, and the handles are illustrated in Figures 24-26. One control handle (702) is connected to the proximal end of the recovery sheath (151) and another control handle (710) is connected to the proximal end of the inner catheter (372).

Daniel meets the limitation *"distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel."* This language is considered to be significantly broad enough to encompass the structure disclosed by Daniel because little structural requirements are actually recited.

a. The examiner considers *"distal portion"* to be any portion of the inner catheter that is distal to the most proximal point. Any distal portion of the inner catheter that extends beyond the distal end of the sheath meets this limitation. Daniel shows the inner catheter (172) to include a *"distal portion"* that extends distally of the sheath (151), so Daniel meets this limitation.

a. The term *"sufficient length"* is significantly broad enough to encompass any length of tubing. Clearly, the inner catheter of Daniel has "sufficient length" to allow the sheath to track over it, because this is how the device functions to retrieve the filter. The length of the *"distal portion"* can be changed by simply choosing a different point along the length of the catheter. Also, the extent to which the inner catheter extends distally beyond the sheath can be changed by moving the tubes relatively to one another. Therefore, Daniel meets this limitation in various ways and a *"distal portion"* with a length at least as long as the filter can be defined.

b. "... to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel" is considered to be a recitation of intended use. The prior art need only to be capable of performing the function set forth the in claim. Since the Daniel device is made of highly flexible materials (column 8, lines 61-67), meets all of the structural requirements, and functions similarly to Appellant's device, Daniel is considered to be capable of being deployed in a curved vessel.

Inner catheter (372) can be locked onto the guide wire (26) by way of a threaded connection between the handle (710) and a locking mechanism that includes a guide wire clamp (720) and a collet (718). The recovery sheath control handle (702) is locked with the inner catheter control handle (710) by a stop (708) that prevents the handles (702,710) from becoming separated but allows the handles to slide relative to one another.

Regarding claims 36,46,56, and 57, the language *"may be up to"*, *"may be up to approximately"*, and *"may extend up to"* is significantly broad to include any length less than the stated dimension. Therefore, the Daniel device meets this limitation, since the recovery sheath is clearly shorter than the inner catheter.

Daniel discloses steps of using the device in column 10 that include advancing the inner catheter and recovery sheath over a guide wire, locking the inner catheter to the guide wire, advancing the recovery sheath over the filter to collapse it, and removing the entire system from the patient's body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel in view of US Patent No. 5,201,757 to Heyn et al.

Daniel includes all the limitations of claims 41 and 51, except that the position of the handles is switched so that control handle of the recovery sheath is coaxially disposed within the lumen of the control handle of the inner catheter. Heyn discloses a device with control handles for sheaths that move relative to one another. Heyn teaches that the control handle (60) for the inner catheter (44) can be disposed within the control handle (56) of the outer sheath (20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to simply rearrange the control handles of Daniel so that the control handle of the inner catheter is disposed within the lumen of the recovery sheath handle, as Heyn teaches that this is an alternate way to configure control handles of relatively moving sheaths.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al.

Daniel fails to state that the inner catheter has greater column strength than the recovery sheath. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to form the

inner catheter to have greater column strength than the recovery sheath, because applicant has not disclosed that the combination of these material properties provides an advantage or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the combination of material properties disclosed by Daniel, because the Daniel device achieves the same objective of tracking a recovery sheath over an inner catheter to retrieve a filter. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. With ever changing surgical techniques and varying anatomies of patients, one of ordinary skill in the art at the time the invention was made would be capable of altering the relative column strengths of the tubes of the Daniel device to accommodate the requirements of a particular surgical procedure.

(10) Response to Argument

Issues 1-3:

Appellant's arguments filed 7/17/06 have been fully considered but they are not persuasive. Appellant argues that Daniel does not meet the requirement *"distal portion of the inner catheter has sufficient length to allow the distal end of the recovery sheath to track thereover to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel."*

As discussed above, this language is not considered to define a specific length of tubing and is significantly broad enough to encompass the structure disclosed by Daniel. Breaking down this language, one can see that little structural requirements are set forth in this recitation:

a. Appellant argues that only the enlarged tip (180) of the inner catheter is the distal portion and does not have *"sufficient length..."* For clarification, the examiner considers *"distal portion"* to be any portion of the inner catheter that is distal to the most proximal point, not just the enlarged tip (180). An infinite number of *"distal portions"* can be defined by changing the point along the tube that defines the separation of proximal and distal portions. Therefore, a *"distal portion"* with a length at least as long as the filter can be defined on the Daniel inner catheter.

b. The claims do not necessarily require the entire *"distal portion"* of the inner catheter to extend distally of the distal end of the recovery sheath. Any portion of the distal portion inner catheter that extends beyond the distal end of the sheath meets this limitation. Daniel shows the inner catheter (172) to include a *"distal portion"* that extends distally of the sheath (151), and the extent to which the inner catheter extends beyond the sheath can be changed by moving the tubes relatively to one another.

c. The term *"sufficient length"* is significantly broad enough to encompass any length of tubing. Appellant's disclosure does not define a specific length of tubing that defines the *"distal portion."* Clearly, the inner catheter of Daniel has *"sufficient length"* to allow the sheath to track over it, because this is how the device functions to retrieve the filter. The length of the *"distal portion"* can be changed by simply choosing a different point along the length of the catheter. Therefore, a *"distal portion"* with a length at least as long as the filter can be defined on the Daniel inner catheter.

d. *"... to reduce the possibility that the recovery sheath will straighten the body vessel when deployed in a curved portion of the body vessel"* is considered to be a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the Daniel device is made of highly flexible materials (column 8, lines 61-67), meets all of the structural requirements, and functions similarly to Appellant's device, Daniel is considered to be capable of performing this function. Further, vascular treatment devices are designed to accommodate tortuous pathways of vessels.

e. How can the reduction of the *"possibility"* of vessel straightening be measured? Appellant's disclosure contains no parameters for determining this statistic.

Issue 4:

Appellant's arguments filed 7/17/06 have been fully considered but they are not persuasive. Appellant argues that it is not obvious to modify the materials of the Daniel so that the inner catheter has greater column strength than the sheath (claim 38), but Appellant has not disclosed that the combination of these material properties provides an advantage or solves a stated problem. This combination of materials is simply disclosed as an alternative to a sheath with greater column strength than the inner catheter (claim 37), so, by Appellant's own disclosure, the device performs equally well with the combination of material properties disclosed by Daniel. With ever changing surgical techniques and varying anatomies of patients, the relative

column strengths of the tubes of the Daniel device could by modified to accommodate the requirements of a particular surgical procedure. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Sarah Webb Sarah K. Webb

Conferees:

Anhtuan Nguyen

Greg Vidovich